

Exhibit D

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AND SRI LANKA

September 29, 2020

VIA ECF

The Honorable Robert Kugler
Senior United States District Court Judge
District of New Jersey

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the conference with the Court on September 30.

1. Deposition Protocol

The parties have exchanged versions of the fact witness deposition protocol used in the *Benicar* litigation edited in attempt to address, among other differences unique to these proceedings, the possibility that a number of foreign nationals from China, India, Israel, and other countries might be deposed in this action, and the impact COVID-19 may have on all of the depositions.

On September 26, 2020, the parties had a teleconference with Judge Schneider during which they discussed some of the challenges presented by the foreign national deponents and COVID-19, especially given the Court's suggestion that depositions of Defendants' employees might begin on January 15, 2021, *see* ECF No. 575, such as: (i) foreign laws restricting depositions where foreign national deponents reside; (ii) ongoing travel restrictions throughout the world due to COVID-19, including mandatory quarantines for travelers; and (iii) time zone differences and

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3. Rule 34 Discovery of Consumer and TPP Class Representatives

During the teleconference with Judge Schneider on September 26, 2020, Defendants proposed serving document requests pursuant to FRCP 34 on the consumer and TPP class representatives, as the Plaintiff Fact Sheets the Court previously approved by the Court do not cover the various categories of information that are pertinent to the question whether any of the proposed class representatives can satisfy the requirements of Rule 23.² The Court advised that Defendants should attach those requests to this submission so that the parties could meet and confer about them, and the Court could then approve sets of requests without objection. The same process the Court utilized in approving the Rule 34 requests Plaintiffs served on Defendants.

Plaintiffs' theory is that, had the consumers been aware of issues with the sartans, they would have not purchased them. As a result, Plaintiffs claim that the putative consumer class is entitled to a return of its sartan "purchase" price – all or a portion of the deductibles they paid under the plan(s) attributable to purchases of the sartans, and each co-pay the consumer class paid under their individual plan(s) for sartan purchases. Defendants' theory is that, had the consumer class not purchased the sartans, each class member would have been required to "purchase" (via deductible and co-pay) a highly individualized replacement drug prescribed by his/her particular doctor to treat their hypertension. The replacement drug may be a different generic drug, or it may be the branded version of the sartan, or it may be a different branded drug altogether.

With regard to discovery then, if the consumer class representative's replacement drug co-pay (a fixed amount the consumer pays for each specific prescription, calculated based on how each plan has chosen to treat that specific prescribed drug for that plan year or portion thereof (also called PDL tier placement)) under the specific plan was the same or more than the sartan co-pay, the consumer class representative has not been injured. If the co-pay was the same or more only during a certain period of time, the consumer class representative's damages would be reduced by that amount. Moreover, the plan's: (1) deductible obligations (the amount the plan member must pay out of pocket before the plan will pay any prescription expenses); and (2) the yearly and plan duration "maximum out-of-pocket" caps on prescription drug costs (the absolute most a plan member will have to pay toward prescription costs in a given year or over the life of a plan membership) may mean that, in light of a replacement drug which costs more than the sartan, the consumer class representative would have had less or none of his deductible attributable to his damage calculation and/or, at an earlier point in time, "maxed out" his damages.

Each of these theories require discovery of information as to each of the consumer class representative's plan(s) that provided for coverage of prescription drugs for the consumer during

² Defendants first raised their intention to serve similar document requests on Plaintiffs on January 14, 2020. See Davis email, attached as Exhibit B.

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the relevant period (2010-2018). Specifically, Defendants and the Court require, among other information:

- The description of each plan under which the class representative was at any point covered during the relevant 8 years (2010-2018) (this may be several plans for any one consumer class representative) and the yearly prescription drug deductible related thereto;
- Where the sartans fell on the consumer class representative's plan's preferred drug list (PDL) by "tier," pursuant to each amendment of each plan's PDL, usually every 6 months (the PDL tier drives the co-pay);
- The actual co-pay for that sartan/tier pursuant to the plan or PDL at each amendment thereof;
- The consumer class representative's plan's maximum out-of-pocket caps on the amount required to be paid for prescription drugs pursuant to each plan amendment;
- The replacement drug(s) which would have been prescribed for the consumer class representative at any relevant point in time (as the choice may change over the relevant time period based on drug development, patient health, and patient history) had the alleged issues with the sartans been made known (obtained via relevant consumer class representative health care provider);
- Where the replacement drug fell on the consumer class representative's plan's PDL by tier at each amendment of the plan's preferred drug list, usually every 6 months (the PDL tier drives the co-pay)³;
- The actual co-pay for that replacement drug/tier pursuant to the plan or PDL at each amendment;
- Whether and when in each plan coverage year the consumer class representative reached his/her maximum out-of-pocket caps for prescription drugs; and

³ Generally, diuretics, ACE inhibitors, ARBs (the sartans) and calcium channel blockers in some format are first line pharmaceutical treatments for hypertension. Other hypertension medications include Beta-blockers, Alpha blockers, Alpha-2, Receptor Agonists, Central agonists, Peripheral adrenergic inhibitors, Vasodilators, and, obviously, a health care provider would have to tailor his replacement drug decision to the needs and personal medical history of his patient. The sheer number of options for replacement drug suggests the variety of different copays in play.

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- The relevant TPP plan or claims administrator's computerized summary records of deductibles and co-pays paid by the consumer class representative for the sartans, as they are likely to have the most complete records of deductibles and co-pays paid, any credits given, and maximum out-of-pocket amounts reached.

Class certification requires that putative class members have suffered damage. The above discovery, among other categories of information requested, is necessary to determine whether the putative class representatives have been injured and, if so, whether they have been in a way that satisfies the requirements of Rule 23. Defendants are attaching Rule 34 discovery requests to be served on the Consumer and TPP Class Representatives as Exhibits C-E.

4. Plaintiff Fact Sheets – Requests for Orders to Show Cause

(a) Cases Addressed at the August 26, 2020 Case Management Conference

As a preliminary matter, Defendants note that the Court issued four show cause orders returnable at the September 30, 2020 Case Management Conference. Subsequent to last month's CMC, voluntary dismissals were filed in two of those matters:

- Thompson, Kim - 1:19-cv-15135
- Needy, Lenny - 1:19-cv-15051

Two cases remain subject to an order to show cause at the September 30, 2020 Case Management Conference for failure to substantially complete a PFS:

	Plaintiff	Civil Action No.	Law Firm	Deficiencies
1.	Stano, David	1:19-cv-18080	Gennusa Piacun & Ruli	I.C.2 - Failed to attach records I.D.1 - Failed to attach records I.D.2 - Failed to respond I.D.3 - Failed to respond I.D.4 - Failed to respond I.D.5 - Failed to respond I.D.6 - Failed to respond